15

## CLAIMS

- needle-guide device, particularly 1. ultrasound probes, or the like, comprising a base body having means for connection to the probe and at least one elongated guide hole for an elongated, diagnostic or surgical tool, characterized in that said needle-guide device (2, 12) is made of at least two removably connectable parts (102, 112; 202, 212), which are shaped in such a manner that each of them forms complementary parts (602, 702; 512, 612, 712, 812, 912) of the peripheral delimiting wall of said elongated guide hole for a needle (3), which peripheral wall parts (602, 702; 512, 612, 712, 812, 912) complete each other when said two parts (102, 112; 202, 212) of the needle-guide device (2, 12) are connected, thereby forming said elongated guide hole for guiding needle with a 360 degree covering delimiting wall.
- 2. A needle-guide device as claimed in claim 1, characterized in that the two parts (102, 112, 202, 212) of the needle-guide device (1, 12) have mutual 20 abutment surfaces (602, 512, 812) which are tangent or secant to the elongated guide hole for guiding the needle (3), whereas said elongated guide hole obtained by a combination of grooves (702, 612, 712, 912) which are formed either integrally on one of the 25 mutual abutment surfaces of one of the two parts (102, 112, 202, 212) of the needle-guide device (2, 12) or partly on one and partly on the other of the two abutment surfaces of both parts of the needle-guide 30 device.

- 3. A needle-guide device as claimed in claim 1 or 2, characterized in that the separation plane between the two parts of the needle-guide device (2, 12) is parallel to the axis of the elongated guide hole and secant or substantially tangent to the hole.
- 4. A needle-guide device as claimed in one or more of the preceding claims, characterized in that said elongated guide hole has a section which corresponds to the outer section of the needle, with the wall of the elongated guide hole adhering to the whole needle surface.
- 5. A needle-guide device as claimed in one or more of the preceding claims 1 to 3, characterized in that said elongated guide hole has polygonal sections, particularly square or rectangular sections, said square or rectangular sections having such a size as to be able to inscribe therein the cylindrical or elliptical or oval section of the needle and generating needle-guiding surfaces tangent to the outer surface of the needle.
- 6. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the needle-guide device (2, 12) is composed of at least two removable parts, at least one base part (102, 112) and at least one second part (202, 212), which two parts are separated from each other by a separation surface (512, 612, 812) whose cross section is a broken rectangular curve, and forms a succession of alternate and parallel complementary engageable ribs, there being provided, in the opposite mutual abutment surfaces of

10

15

30

the ribs of one or both of the two parts (102, 112, 202, 212) of the needle-guide device (2, 12) grooves (712, 912) having such a size and shape as to form together said elongated guide hole.

- 7. A needle-guide device as claimed in claim 6, characterized in that the broken rectangular lineshaped separation surface between said two parts of the needle-guide (2, 12) has constant or variable widths to generate guiding holes aligned on one or more planes and with different relative positions.
  - 8. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the needle-guide device (2, 12) may be divided in such a manner as to consist of more than two parts, instance three parts, shaped in such a manner as to form complementary parts of the peripheral delimiting wall of said elongated guide hole.
- 9. A needle-guide device as claimed in one or more of the preceding claims, characterized in that it is (102) for connection an composed of a base 20 ultrasound probe (1), which has an abutment or support surface (602) for the second part (202) of the needlequide device (2), which second part (202) has in turn least one longitudinal groove (702) whose size corresponds to the needle size, and forms the side 25 walls and a wall transverse thereto for delimiting the needle-guiding hole, whereas its support surface (602) on the base (102) of the needle-guide device (2) forms the missing wall of the elongated guide hole, when the two parts (102, 202) of the needle-guide device are

20

25

connected.

10. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the two mutual abutment surfaces of the two parts (102, 112, 202, 212) of the needle-guide device (2, 12) have each a groove whose width corresponds to the width of the needle and a partial depth relative to the corresponding dimension of the needle, the two grooves being coincident and completing mutually when the two parts (102, 112, 202, 212) of the needle-guide device (2, 12) are connected, thereby forming the elongated guide hole for guiding the needle (3).

11. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the base part (102, 112) of the needle-guide device (2, 12) has at least a longitudinal groove in the surface abutting against the second removable part (202, 212) of the needle-guide device (1, 12), for engagement of longitudinally continuous or discontinuous extensions of the side walls of a longitudinal groove formed in said second removable part (202, 212) of the needleguide device, thereby forming the bottom longitudinal groove of the base (102, 112), the missing completing wall of the elongated guide hole, whose additional delimiting walls are formed by the bottom of the longitudinal groove in said second part (202, 212) of the needle-guide device, the side walls of said groove and the extensions of said side walls of the groove in said second part of the needle-guide device.

- 12. A needle-guide device as claimed in claim 11, characterized in that, alternatively, instead of two extensions of the side walls of the longitudinal grooves in the second part (202, 212) of the needle-guide device (2, 12), the second part (202, 212) of the needle-guide device (2, 12) may be arranged to have a single extension of one of the two side walls of the longitudinal groove, whereas the other extension may be provided on the base part (102, 112), as an extension of the opposite side wall of the longitudinal groove in the base part of the needle-guide device, whereby each of the two parts (102, 112, 202, 212) of the needle-guide device (2, 12) forms two of the opposite walls of the elongated guide hole.
- 13. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the arrangement of the extensions of the side walls of the grooves in the two parts (102, 112, 202, 212) of the needle-guide device (2, 12) is alternate and complementary over the length of the two extensions in the longitudinal direction of the grooves, either on one side and along the two opposite sides.
  - 14. A needle-guide device as claimed in one or more of the preceding claims, characterized in that it has means (6, 7, 106, 107, 9, 409, 802, 902) for centering and partially interlocking the two parts (102, 202) of the needle-guide device (2).
- 15. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the two parts (102, 112, 202, 212) of the needle-guide

10

15

20

25

device (2, 12) have removable mutually locking means (8).

16. A needle-guide device as claimed in claim 15, characterized in that the two parts (102, 112, 202, 212) of the needle-guide device (2, 12) have mutually clamping screw threaded means (8).

17. A needle-guide device as claimed in claim 16, characterized in that the mutually clamping screw threaded means (8) of the two parts (102, 112, 202, 212) of the needle-guide device (2, 12) have means (206, 306, 113) for engaging said two parts of the needle-guide device in an non-separable condition, and in a incompletely clamped condition.

18. needle-guide device, particularly Α ultrasound probes, or the like, comprising a base body having means for connection to the probe and at least one elongated guide hole for receiving a needle-like surgical tool, characterized in that it has a plurality of elongated guide holes for guiding a plurality of surgical tools arranged with their axes coincident with a single plane or having axes arranged on more planes, particularly having hole axes arranged at the vertices ideal polygonal elements, such as triangles, quadrilaterals, or the like, or in any other different mutual arrangement.

19. A needle-guide device as claimed in claim 18, characterized in that it has, individually or in combination, the characteristics of one or more of claims 1 to 17.

10

15

20

25

30

20. A needle-guide device as claimed in claims 18 or 19, characterized in that said needle-guide device (12) is composed of a base part (112) to be secured, for instance, to an ultrasound probe (11) and of a removable part (212), a separation plane or surface 812) being provided between the at least two parts (112, 212), which is parallel to the axis of the corresponding elongated guide hole, and is secant or at the corresponding least tangent to hole, and combinations of grooves (612, 712, 912) and walls in the mutual abutment surfaces of said two parts (112, which, by their mutual engagement, form complementary parts of the surfaces delimiting the two, three or more holes of the needle-quide device, so that, by separating said at least two parts (112, 212), all the elongated guide holes are longitudinally open on at least one portion of a side.

21. A needle-guide device as claimed in one or more of claims 18 to 20, characterized in that it includes three elongated guide holes and wherein the needle-guide device (12) is divided into a base (112) and a second part (212) to be removably fastened to the base, the base (112) of the needle-guide device (12) having a surface (512) whereby it abuts against the second part (212) of the needle-guide device, wherein a first groove (612) is provided in a median position, in turn having a second groove (712) in its bottom wall, which is designed to form two longitudinal side walls and a longitudinal bottom wall of one of the elongated guide holes for one of the needles (3), whereas the

25

second part (212) of the needle-guide device (12) has, on the surface turned toward the abutment surface (512) of the base part (112), a longitudinal median rib (812) which coincides with the longitudinal median groove (612) in the base part (112) and forms the missing 5 delimiting surface of the corresponding elongated guide hole, thereby completing the delimiting surfaces formed by the second groove (712), whereas, in the surfaces of the second part (212) of the needle-guide device (12), on the two sides of the longitudinal median rib 10 (812), longitudinal grooves (912) are provided which form, with the bands of the abutment surface (512) of the base (112) on both sides of the first groove (612), the delimiting surfaces of the two additional elongated guide holes. 15

- 22. A needle-guide device as claimed in claim 21, characterized in that the grooves (712, 912) which form a portion of the side walls and a wall transverse thereto for delimiting the elongated guide hole are provided partially in both opposite mutual abutment surfaces of the two parts (112, 212) of the needle-guide device (12).
- 23. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the needle-guide device (2) has a slender or tapering head (9), particularly having rounded edges, especially being wedge-shaped.
- 24. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the30 whole needle-guide device (9) has a shape tapering

toward the front end, especially a wedge shape.

- 25. A needle-guide device as claimed in one or more of the preceding claims, characterized in that at least one elongated guide hole for guiding at least one needle is inclined in a manner corresponding to the wedge-shaped profile of the needle-guide device (2).
- 26. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the front head (9), also perforated (209), is arranged to be a single piece, and preferably made of one piece with the base part (102) of the needle-guide device (2).
- 27. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the front head (9), which is integral with the base (102) and the second removable part (202) of the needle-guide device (2) have complementary mutually engaging means (409, 802, 902).
- 28. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the 20 through hole (409) in said head part (9) is widened on at least one side or for a portion of its delimiting surface inside the head (9), the second part (202) of the needle-guide device (2) having a wall extension (802, 902) at its end which may be axially engaged in 25 the through hole (409) of the front head (9), and which coincident widened portion with said is complementary thereto so as to form and/or complete the delimiting wall of the through elongated guide hole, at least on a few sides, even at the front head (9) of the 30

10

15

20

25

30

needle-guide device (2).

- 29. A needle-guide as claimed in one or more of the preceding claims, characterized in that the second part (202) of the needle-guide device (2) has said extensions (802, 902) on two opposite sides and in the form of front extension wings of the two side walls of the groove (702) provided in said second part (202) of the needle-guide device, whereas the front head (9) of the needle-guide device has complementary widened portions in the corresponding walls of the through hole (409).
- 30. A needle-guide device as claimed in one or more of the preceding claims, characterized in that an extension wing (902) is also provided from the bottom wall of the groove (702) of the second part (202) of the needle-guide device, the front head (9) of the needle-guide device being arranged to be accordingly widened even at said extension wing (902) of the bottom side of the groove (702) of the second part (202) of the needle-guide device.
- 31. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the extension wings (802, 902) of the side and/or bottom walls of the groove (702) in the second part (202) of the needle-guide device are thinner than the wall of the second part (202) of the needle-guide device and than the head (9) of the needle-guide device, whereby an abutment step is formed between the front end of the second part (202) of the needle-guide device and the facing rear end side of the front head (9).

15

- 32. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the front head (9) of the needle-guide device, which is integral with the base part (102) of the needle-guide device, has a through aperture (509) which communicates with the elongated guide hole provided therein at at least one of the sides of said head, preferably at one of the two transverse sides, not coinciding with the extension wings (802, 902) of the second part (202) of the needle-guide device and particularly at the side of the base part (102) of the needle-guide device which is opposite the second part (202) of the needle-guide device and meant to adhere against or turned toward the probe, whereas in the front head (9), the needle is only substantially guided on three sides and through less than 360° at least in coincidence with the through aperture (509).
- 33. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the front head (9) has a steeper tapering inclination in the portion projecting beyond the aperture (509) on one of the sides, and that the needle projection aperture (209) is provided in the inclined front side, and is slot-shaped due to the inclination of the front end of the head (9).
  - 34. A needle-guide device as claimed in one or more of the preceding claims, characterized in that the length of the front head (9) wherein each needle (3) is guided only on a few sides is relatively small as compared with the length of the rest of the needle-

guide device in which the elongated guide hole has a continuous delimiting surface.

- 35. A needle-guide device as claimed in claim 34, characterized in that the front head (9) has needle guiding surfaces covering less than 360° and wherein the missing part of the guiding wall is alternated in different positions through successive sectors of the head (9).
- 36. A needle-guide device as claimed in one or more of claims 33 to 35, characterized in that, at the more tapered front end, the elongated guide hole delimiting walls are continuous and made of one piece, as well as directly accessible from the aperture (209) wherefrom a needle (3) projects.
- 37. A combination of a needle-guide device and an 15 ultrasound probe comprising a handgrip part (101, 111) and a scan head (201, 211), characterized in that the of the needle-guide device base (102, 112) removably attachable (4, 312, 312') to the probe body (1, 11) in a stable and predetermined position, said 20 base (102) having one or more shape mating extensions (609, 501, 403, 502, 401, 312, 312', 311) which adhere to a portion of the outer surface of the ultrasound probe body and/or mutual interlock engagement means, as 25 well as clamping means (4).
  - 38. A combination as claimed in claim 37, characterized in that the needle-guide device (2, 12) is as claimed in one or more of the preceding claims 1 to 36.

15

20

25

- claimed claim combination as in 39. Α characterized in that the needle-guide device (2) has a tapered front head (9) and the probe is an endocavitary which typically has a substantially probe (1),other similar shape, also cylindrical or elongated and having a rounded head (101), the base (102) of the needle-guide device having a surface whereby it rests on the probe case only in a few partial portions of the longitudinal extension and particularly in the end portions of the base (102) of the needle-guide device.
- 40. A combination as claimed in claim 39, characterized in that the facing surfaces of the base (102) of the needle-guide device and of the probe case (1) have complementary centering projections and recesses (402, 502, 401) arranged over their length.
- 41. A combination as claimed in claim 39 or 40, characterized in that the probe case may have recesses (501) for accommodating supporting feet or extensions (609) of the base (102) of the needle-guide device, provided at least at the ends thereof.
- claim combination as claimed in 41, 42. Α characterized in that the tapered front head (9) of the needle-guide device has an engagement extension (609) on the side turned toward the probe case (1), which is designed to engage in a recess (510) of the probe case (1), in such a manner that the tapered end of said (9) is connected thereto without front head substantially forming steps or discontinuities external the surface of the probe case.

25

- 43. A combination as claimed in one or more of the preceding claims 37 to 42, characterized in that the engagement means between the front head (9) of the needle-guide device and the probe (1) form means for holding the needle-guide device base (102) in position, whereas the needle-guide device is removably secured to the probe by means of a clamping collar (4) provided at the rear end portion of the needle-guide device.
- 44. A combination as claimed in one of claims 37 or 38, characterized in that it includes an external 10 ultrasound probe (11) having a bulged shape and a wider head (211, 311) as compared with the handgrip (111), head (211)has its wherein the probe greatest circumference in an intermediate position between the front end and the portion connected to the handgrip, 15 whereas the needle-guide device has a base (212) having preferably symmetrically coincident (312) before the greatest circumference of the probe head, and an extension (312') with a fastening screw which overlaps the rear side (311) of the widened head 20 (211) against which the fastening screw is tightened.
  - 45. A combination as claimed in one or more of the preceding claims 37 to 44, characterized in that at least one elongated guide hole is arranged to have such an inclination with respect to the central axis of the cone of view of the ultrasound probe and at least one needle falls within the probe imaging region upon scanning, whereas at least one, preferably all the other needles have predetermined and fixed positions relative to the former.